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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,538	05/02/2005	Kei Kiribayashi	271390US0PCT	1631
22850 7590 07/13/2007 OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER HENRY, MICHAEL C	
			ART UNIT 1623	PAPER NUMBER
			NOTIFICATION DATE 07/13/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/533,538

Applicant(s)

KIRIBAYASHI ET AL.

Examiner

Michael C. Henry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11-17 is/are allowed.
- 6) ☒ Claim(s) 1-10 and 18-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>05/02/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-20 are pending in application

Information Disclosure Statement

The information disclosure statement filed complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-10, 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6-10 provide for the “use of adenosine triphosphate ” but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 18-19 recites the phrase “characterized by administering adenosine triphosphate”. However, the claim is indefinite. More specifically, it is unclear to whom or to what is said adenosine triphosphate being administered.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 6-10 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Shukolyukov et al. (Mitokohondrii, Mol. Mekh. Ferment. Reakts., Mater. Vses. Simp. Biokhim. Mitokhondrii, 6th (1972), Meeting Date 1970, 189-93. Editor (s): Severin, S. E. "Nauka": Moscow, USSR).

In claim 1, applicant claims "A peritoneal dialysate comprising adenosine triphosphate or a salt thereof. Shukolyukov et al. disclose applicant's composition comprising adenosine triphosphate (ATP) (see abstract). It should be noted that Shukolyukov et al.'s composition comprises the same compound (ATP) or ingredient as applicant's and should also be a peritoneal dialysate. Furthermore, it should be noted that it is well settled that "intended use" of a composition or product, e.g., a peritoneal dialysate, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack*

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114, USPQ 161. Claim 2 is drawn to the peritoneal dialysate as described in claim 1, further comprising glucose and an electrolyte. Shukolyukov et al. disclose applicant's composition comprising adenosine triphosphate (ATP), glucose and an electrolyte (KCl or $K^+ + Cl^-$) (see abstract). It should be noted that Shukolyukov et al.'s composition comprises the same compounds or ingredients as applicant's and should also be a peritoneal dialysate. Furthermore, it should be noted that it is well settled that "intended use" of a composition or product, e.g., a peritoneal dialysate, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Claim 3 is drawn to a preventive or therapeutic agent for peritoneal injury, comprising adenosine triphosphate or a salt thereof as an active ingredient. Shukolyukov et al. disclose applicant's composition comprising adenosine triphosphate (ATP) (see abstract). It should be noted that Shukolyukov et al.'s composition comprises the same compound (ATP) or ingredient as applicant's and should also have the same effect on peritoneal injury. Furthermore, it should be noted that it is well settled that "intended use" of a composition or product, e.g., for peritoneal injury, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Claim 4 is drawn to a therapeutic agent for cell injury caused by sugar, comprising adenosine triphosphate or a salt thereof as an active ingredient. Shukolyukov et al. disclose applicant's composition comprising adenosine triphosphate (ATP) (see abstract). It should be noted that Shukolyukov et al.'s composition comprises the same compound (ATP) or ingredient as applicant's and should also have the same effect on cell injury. Furthermore, it should be noted that it is well settled that "intended use" of a composition or product, e.g., for cell injury, does not further limit claims drawn to a

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composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Claim 5 is drawn to the agent as described in claim 4, wherein the cell injury caused by sugar is peritoneal mesothelial cell injury caused by glucose. Shukolyukov et al. disclose applicant's composition or agent comprising adenosine triphosphate (ATP) (see abstract). It should be noted that Shukolyukov et al.'s composition comprises the same compound (ATP) or ingredient as applicant's and should also have the same effect on peritoneal mesothelial cell injury. Furthermore, it should be noted that it is well settled that "intended use" of a composition or product, e.g., for peritoneal mesothelial cell injury, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

Allowable Subject Matter

The following is an examiner's statement of reasons for allowance: The examiner has found claims 11-17 to be unobvious over the prior art of record and therefore to be allowable over the prior art of record. The present invention relates a peritoneal dialysis method, characterized by employing a dialysate comprising adenosine triphosphate or a salt thereof in an effective amount. The very relevant prior art document (Shukolyukov et al; Mitokohondrii, Mol. Mekh. Ferment. Reakts., Mater. Vses. Simp. Biokhim. Mitokhondrii, 6th (1972), Meeting Date 1970, 189-93. Editor (s): Severin, S. E. "Nauka": Moscow, USSR) to this invention discloses a composition comprising adenosine triphosphate but does not disclose nor suggest the use of said composition in a peritoneal dialysis method as claimed in the instant invention.

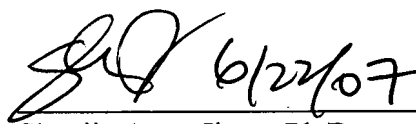
Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry


Shaojia Anna Jiang, Ph.D.
Supervisory Patent Examiner
Art Unit 1623

June 21, 2007.